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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/006,797	12/04/2001	John David Fraser	12669-002001/30072UPS00	9884

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EXAMINER	
JUEDES, AMY E	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 10/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/006,797	FRASER ET AL.	
	Examiner	Art Unit	
	Amy E. Juedes, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 August 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-11,13-18 and 21-39* is/are pending in the application.

4a) Of the above claim(s) *7-9,14,17,18 and 21-38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-6, 10-11, 13, 15-16, and 39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment and remarks, filed 8/29/06, are acknowledged.

Claim 1 has been cancelled.
Claims 2-5, 10-11, 13, and 15-17 have been amended.
Claim 39 has been added.
Claims 2-11, 13-18, and 21-39 are pending.

Claims 7-9; 14, 17-18 and 21-38 stand withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claims 2-6, 10-11, 13, 15-16, and 39 are being acted upon.

2. The rejections of the claims under 35 112 second paragraph, as outlined in sections B) and C) of the previous office action are withdrawn in view of Applicant's amendment to the claims to remove the terms "fully functional", "little or no ability", and "immunomodulatory antigen".

3. The rejections of the claims under 35 U.S.C. first paragraph are withdrawn in view of Applicant's amendment to the claims to remove the recitation of targeting molecules that "mimic" a superantigen, are "structurally" as superantigen, or contain "a part" of a superantigen.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-6, 10-11, 13, and 15-16 stand rejected and claim 39 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As set forth previously, A) The terms "immunomodulator" and claim 2 is indefinite because it is ambiguous as the direction (positive or negative) or degree of said immunomodulator. The terms are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the metes and bounds of the invention.

Applicant's arguments filed 8/29/06 have been fully considered, but they are not persuasive.

Applicant argues that the term "immunomodulator" is a well defined term in the art, and that the instant immunomodulator either enhances or suppresses an immune response, and does not enhance and suppress an immune response at the same time.

However, the term "immunomodulator", as conceded by Applicant, encompasses both enhancing an suppressing an immune response. The instant claims are drawn to a product, a mutated superantigen coupled to an antigen. If the product enhances an immune response, it is not clear how the product could also suppress an immune response, since these are mutually exclusive possibilities. Additionally, it is not clear what degree or type of immunomodulation is required. For example immunomodulation could indicate that an immune pathway is turned on or off, or could also indicate an upregulation or downregulation of a type of immune cell to an unspecified degree. In addition, said immunomodulation could be intermittent, or constant. Therefore, the term immunomodulator is so vague that the metes and bounds of the claims cannot be established.

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 2–6, 10-11, 13, and 15-16 stand rejected under 35 U.S.C. 102(b) as being anticipated by Yamoaoka e al, 1998, Infection and Immunity, vol. 66 pp. 5020-5026.

As set forth previously, Yamaoka teaches a mutated superantigen that has a disrupted/non-fully functional T cell receptor binding site (see materials and methods). Said mutated superantigen is coupled to an antigen (GST, see pg 5022 paragraph 1) and can act as an immunomodulator, in that it can weakly stimulate peripheral blood lymphocytes (see fig. 2). Furthermore, said mutated superantigen is derived from SPE-C, (see pg. 5020, materials and methods). Claim 3 is included since the superantigen was mutated by amino acid substitution. Claim 4 is included since the T cell receptor binding site of the superantigen has been deleted (i.e. is non-functional and therefore not present). Claim 10 and 11 are included since Yamaoka teaches that the superantigen is reversibly coupled to a protein (GST can be cleaved off - see pp. 5022 paragraph 1). Claims 15-16 have been included since the reference

teaches using the mutated superantigen in vivo (i.e. as a pharmaceutical composition or vaccine - see fig. 2, and pg. 5023).

It is noted that a typographical error resulted in the removal of claims 6 and 10 from the heading of the rejection in the previous office action. The claims are clearly mentioned in the text of the rejection (see above) and therefore have been included as being anticipated by Yamoaoka et al.

Applicant's arguments filed 8/29/06 have been fully considered, but they are not persuasive.

Applicant argues that Yamaoka et al. teach that GST was cleaved from the superantigen before the immune modulation activity of the SPEC mutants was tested, and therefore Yamaoka et al. do not teach using a mutated superantigen coupled with an antigen as an immunomodulator.

However, the instant claims are drawn to a product, a superantigen targeting molecule coupled to an antigen. Yamaoka et al. teach said product (i.e. mutated SPE-C coupled to GST). Whether Yamaoka et al. used the product for immunomodulation is not relevant, since a product is a product irrespective of its intended use. Furthermore, the ability to act as an immunomodulator is an inherent property of the mutated SPE-C coupled to GST taught by Yamaoka, whether or not it was tested, since it is the same as the immunomodulator of the instant claims.

6. The following are new grounds of rejection necessitated by Applicant's amendment

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2–5, 11, 13, 15-16, and 39 are rejected under 35 U.S.C. 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. This is a new

matter rejection.

The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically:

A) An immunomodulator comprising a targeting molecule that "includes a Class II MHC binding site" and a T cell receptor binding site of a superantigen, the T binding site having one or more mutations that "reduce its T cell proliferation activity" (Claim 2 and dependent claims 3-5, 11, 13, 15-16, and 39).

B) An immunomodulator wherein the mutated T cell receptor binding site "reduces the T cell proliferation activity to equal to or greater than 10,0000 fold" (Claim 39).

Applicant indicates that support for the limitations of claim 2 can be found on page 3 of the specification, and support for new claim 39 can be found in Table 3 at page 21 of the specification.

A review of the specification fails to reveal support for the new limitation.

Regarding A), the instant specification discloses on pg. 3 a targeting molecule that mimics a superantigen but does not include a fully functional T-cell receptor binding site and a targeting molecule which is structurally a superantigen but for a disrupted T-cell receptor binding site. However, there is no disclosure of a targeting molecule that specifically "includes a class II binding site", as now claimed. Furthermore, the targeting molecules disclosed on page 3 include those without a fully functional T cell receptor binding site, or those that have little or no ability to activate T cells. However, these generic disclosures are not adequate to support claims which specifically recite that the T cell binding site "reduces T cell proliferation activity".

Regarding B), the instant specification on page 21 discloses specific targeting molecules such as SMEZ-2 W75L that reduce T cell proliferation to greater than 10,000 fold. However, this specific example is not adequate to support the more generic claims of the instant application which are drawn to an immunomodulator comprising any superantigen with any mutation in the T cell binding site.

8. No claim is allowed.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E. Juedes, Ph.D. whose telephone number is 571-272-4471. The examiner can normally be reached on 8am - 5pm, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Amy E. Juedes, Ph.D.
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September 29, 2006

10/24/06
G.R. EWOLDT, PH.D.
PRIMARY EXAMINER